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10/527,618	03/11/2005	Kwok-Leung (Jacky) Au-Yeung	213-0084US	5241

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EXAMINER

PANDE, SUCHIRA

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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05/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,618	Applicant(s) AU-YEUNG ET AL.	
	Examiner Suchira Pande	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-36 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-36 is/are allowed.
- 6) ☒ Claim(s) 16-28 and 31 is/are rejected.
- 7) ☒ Claim(s) 29 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on March 8, 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This office action is in response to an amendment filed on March 8, 2007.

Claims 16-32 were previously pending. Applicant amended claim 16; and added new claims 33-36.

Claims 16-36 are currently pending and will be examined.

Drawings

2. Applicant's amendment overcame the objections to the Drawings. Drawings submitted on March 8, 2007 are acceptable.

Response to Argument re 102 Rejections

3. Claims 20 and 21 were rejected under 35 U.S.C. 102(b) as being anticipated by Ciccolini et al. (1999) Bioprocess Engineering 21: pp 231-237 and evidenced by Wan et al. (US Pat. 5,837,529 issued November 17, 1998).

Applicant argues that Ciccolini et al. as evidenced by Wan does not teach a cell lysis process wherein cells in suspension are lysed in the presence of controlled stream of gas bubbles.

Ciccolini et al. teaches on page 236 bottom of par. 5, mixing using "two-impinging-jet" mixing and on page 237 par. 1 teaches mixing of injected potassium acetate and air and separation of the flocculated material from plasmid containing liquor. The air is in form of small bubbles (controlled stream of gas bubbles).

Examiner agrees that Ciccolini et al. does not explicitly teach addition of gas bubbles at time of lysis. However on page 232 par.1 Ciccolini et al. is very emphatic

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about pointing out that "subsequent separation of the plasmid-containing solution from the floating gel-matrix must be carried out under "low" shear conditions in order to avoid the fragmentation of the precipitated chromosomal DNA which will make its subsequent separation from plasmid DNA extremely difficult". Thus Ciccolini et al. provides clear teaching to one of ordinary skill that it is very important to use conditions that will avoid fragmentation of chromosomal DNA. The fact that Ciccolini et al. teach use of gas bubbles to float the precipitated chromosomal DNA, immediately make it obvious to one of ordinary skill that one could use air bubbles during lysis step as well so the chromosomal DNA is subjected to least amount of breakage during the lysis.

Accordingly the 102 rejections against claims 20 and 21 are withdrawn and the claims are rejected under 103 as follows.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ciccolini et al. (1999) Bioprocess Engineering 21: pp 231-237 and evidenced by Wan et al. (US Pat. 5,837,529 issued November 17, 1998) in view of Ciccolini et al. (1999) Bioprocess Engineering 21: pp 231-237 .

Regarding claim 20, Ciccolini et al. teaches a cell lysis process wherein cells in suspension are lysed in the presence of a controlled stream of gas bubbles sufficient to

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cause flotation and separation of a cellular debris component over a clarified lysate component comprising extrachromosomal nucleic acids. (see page 231, par. 3-page 232 par. 1 where cell lysis and floatation of cell debris is taught). On page 236 bottom of par. 5, Ciccolini et al. teaches mixing using "two-impinging -jet' mixing and on page page 237 par. 1 teaches mixing of injected potassium acetate and air and separation of the flocculated material from plasmid containing liquor. The air is in form of small bubbles (controlled stream of gas bubbles). The fact that the cellular debris formed by their method is flocculant material that floats inherently indicates that the controlled stream of air that is mixed creates a controlled stream of gas bubbles is sufficient to cause flotation and separation.

Regarding claim 21, Ciccolini et al. further teaches wherein the lysis process is an in-line process for alkaline lysis of bacterial cells (see page 236, par. 5) as evidenced by Wan et al. who describe in detail the in-line process for alkaline lysis see whole patent, specially see col. 3 where in-line lysis is taught and col. 3, lines 20-21 where alkali is taught as a lysis agent).

Regarding claims 20 and 21, Ciccolini et al. does not explicitly teach addition of gas bubbles at time of lysis. However on page 232 par.1 Ciccolini et al. is very emphatic about pointing out that "subsequent separation of the plasmid-containing solution from the floating gel-matrix must be carried out under "low" shear conditions in order to avoid the fragmentation of the precipitated chromosomal DNA which will make its subsequent separation from plasmid DNA extremely difficult". Thus Ciccolini et al. provides clear teaching to one of ordinary skill that it is very important to use conditions that will avoid

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fragmentation of chromosomal DNA. The fact that Ciccolini et al. teach use of gas bubbles to float the precipitated chromosomal DNA, immediately make it obvious to one of ordinary skill that one could use air bubbles during lysis step as well so the chromosomal DNA is subjected to least amount of breakage during the lysis. Hence it would have been prima facie obvious to one of ordinary skill in the art to use gas bubbles at the time of lysis in view of the teachings of Ciccolini et al. in the method of Ciccolini et al. at the time the invention was made.

Response to Argument re 103 Rejections of claims 16-19

6. Claims 16- 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cuthbertson (WO 99/55837 published November 4, 1999) in view of Theodossiou et al. (1999) Bioprocess Eng. 20: 147-156.

Applicant argues that Cuthbertson does not teach or suggest use of a gas (as per amended claim) during lysis and for floatation of lysis flocculants. Ciccolini et al. as discussed above (see discussion 103 rejection re claims 20 and 21 above) teaches use of gas and the teachings make it obvious for one of ordinary skill to use gas bubbles during lysis and floatation of lysis flocculants.

Accordingly Claims 16- 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuthbertson (WO 99/55837 published November 4, 1999) in view of Theodossiou et al. (1999) Bioprocess Eng. 20: 147-156 and further in view of Ciccolini et al. (1999) Bioprocess Engineering 21: pp 231-237.

Response to Argument re 103 Rejections of claim 22

7. Claim 22 was rejected under 35 U.S.C. 103(a) as being unpatentable over Chevalier (WO 99/37750 published on July 29, 1999). US equivalent of the above WO document (US Pat. No 6,664,049 is being used to point out pertinent sections as it is easier to cite US patents) in view of Ciccolini et al. (1999) Bioprocess Engineering 21: pp 231-237 and Mittlestaedt et al. (US Pat. 6, 268,492 issued July 31, 2001) as evidenced by Theodossiou et al. (1999) Bioprocess Eng. 20: 147-156.

Applicant argues that neither Chevalier, Mittlestaedt or Theodossiou teach or suggest addition of gas at any time during plasmid purification. However as pointed out earlier (see supra for claim 20-21) Ciccolini does teach use of gas for floatation and explicitly teaches its use during neutralization. Contrary to Applicant's arguments presented Ciccolini does make it obvious (see discussion above for claims 20-21) and provide motivation to one of ordinary skill to use gas during lysis. Hence the rejection is being maintained.

Response to Argument re 103 Rejections of claims 23 and claims dependent therefrom

Applicant argues that Cuthbertson does not teach or suggest use of gas (as per the claims for floatation of lysis flocculants. As pointed out earlier Ciccolini et al. teaches use of gas and makes it obvious for one of ordinary skill to use it as the lysis step as well. In view of the above conclusion reached by the Examiner claims 23-28 and 31 are rejected over the respective prior art cited further in view of Ciccolini et al. Accordingly,

Claims 23, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wan et al. (US Pat. 5,837,529 issued November 17, 1998) in view of Cuthbertson

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(WO 99/55837 published November 4, 1999), further in view of Ciccolini et al. (1999) Bioprocess Engineering 21: pp 231-237.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wan et al. (US Pat. 5,837,529 issued November 17, 1998) in view of Cuthbertson (WO 99/55837 published November 4, 1999) as applied to claim 23 above further in view of Gomez et al. (2000) Canadian J. of Chemical Engineering Sciences vol. 78 (4) 785-792; and further in view of Ciccolini et al. (1999) Bioprocess Engineering 21: pp 231-237.

Allowable Subject Matter

8. Claims 32-36 are allowable. Claim 32 was determined to be free of prior art in previous Office Action. Applicant has added new claims 33-36 that depend from allowed claim. Accordingly claims 32-36 is allowable.

Conclusion

9. Claims 16-28 and 31 are rejected over prior art.

10. Claims 29-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims as they are free of prior art.

11. Claims 32-36 are allowable.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande
Examiner
Art Unit 1637

JEFFREY FREDMAN
PRIMARY EXAMINER
5/9/07